20

25





WHAT IS CLAIMED IS:

- 1. A method of contraception which comprises administering for 21 successive days to a female of childbearing age a combination of an estrogen and a progestogen in a contraceptively effective daily dosage in which there is a first phase of 5-8 days 5 where the combination comprises a progestogen equivalent in effect to about 0.065-0.75 mg of norethindrone and an estrogen equivalent in effect to about 23-28 μg of ethinyl estradiol; followed by a second phase of 7-11 days, where the combination comprises a progestogen equivalent in effect to about 0.25-1.0 mg of a norethindrone and an estrogen equivalent in effect to about 23-28 µg of ethinyl 10 estradiol; followed by a third phase of 3-7 days where the combination comprises a progestogen equivalent in effect to about 0.35-2.0 mg of norethindrone in combination with an estrogen equivalent in effect to about 23-28 µg of ethinyl estradiol; and followed by 4-8 days which are free of hormone administration; with the provisos that the progestin dose should increase from the first phase to the 15 second phase to the third phase, that the progestin is desogestrel at a dose in each phase of between of from 0.05-1.0 mg/day and that the dosage of estrogen is kept constant in each phase.
 - 2. The method of claim 1 wherein the estrogen and progestogen are administered orally and the period specificed in each phase is seven days.
 - 3. The method of claim 2 wherein the estrogen and progestogen are administered in admixture.
 - 4. The method of claim 1 wherein the estrogen is selected from the group consisting of 17α -ethinylestradiol, mestranol, estrone, estrone sulfate piperazine salt, estradiol and estriol.
 - 5. The method of claim 1 wherein the estrogen is selected from the group consisting of is 17α -ethinylestradiol or 17α -ethinylestradiol 3-methyl ether.
 - 6. The method of claim 3 wherein the estrogen is 17α -ethinylestradiol.
 - 7. The method of claim 3 wherein the estrogen is 17α -ethinylestradiol 3-methyl ether.
- 8. The method of claim 1 wherein the desogestrel daily dosage is 0.100 mg in the first phase, 0.125 mg in the second phase and 0.150 mg in the third phase and the estrogen daily dosage is 25 μg for each phase.

5

10

15

20

25

30



- 9. The method of claim 1 which comprises administering for 21 successive days to a female of childbearing age a combination of 17α -ethinylestradiol and desogestrel for the first 7 days in a daily dosage equal to 25 μg of 17α -ethinylestradiol and 0.100 mg of desogestrel, for the succeeding 7 days a daily dosage equal to 25 μg of 17α -ethinylestradiol and 0.125 mg of desogestrel; and for the next 7 days a daily dosage equal to 25 μg of 17α -ethinylestradiol and 0.150 mg of desogestrel; followed by 7 days without estrogen and progestogen administration.
- 10. A triphasic oral contraceptive unit having 21 separate dosage units, adapted for successive daily oral administration comprising: 5-8 dosage units containing, in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen and a progestogen at contraceptively effective dosages corresponding in estrogenic activity to 23-28 μg of 17 α -ethinylestradiol and in progestogenic activity to 0.065-0.75 mg of norethindrone as a first phase; followed by 7-11 dosage units containing in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen and a progestagen at a contraceptively effective dosage corresponding in estrogenic activity to 23-28 μg of 17α-ethinylestradiol and in progestogenic activity to 0.25-1.0 mg of norethindrone as a second phase; followed by 3-7 dosage units containing a admixture with a pharmaceutically acceptable carrier, a combination of an estrogen at a contraceptively effective dosage corresponding in estorgenic activity to 23-28 μg of 17α -ethinylestradiol and in progestogenic activity to 0.35-2.0 mg of norethindrone as a third phase; and optionally containing 4-8 additional dosage units free of estrogen and progestogen; with the provisos that the progestin dose should increase from the first phase to the second phase to the third phase, that the progestin is desogestrel at a dose in each phase of between of from 0.05-1.0 mg/day and that the dosage of estrogen is kept constant in each phase.
- 11. The contraceptive unit according to claim 10 wherein the dosage units are in the form of tablets.
- 12. The contraceptive unit according to claim 10 wherein the estrogen is selected from the group consisting of 17α-ethinylestradiol, mestranol, estrone, estrone sulfate, estrone sulfate piperazine salt, estradiol and estriol.
- 13. The contraceptive unit according to claim 10 wherein the estrogen is 17α -ethinylestradiol.

10

15

20

25



- 14. The contraceptive unit according to claim 10 wherein the estrogen is 17α -ethinylestradiol.
- 15. The contraceptive unit according to claim 10 wherein the estrogen is 17α -ethinylestradiol 3-methyl ether.
- 5 16. The contraceptive unit according to claim 10 wherein the estrogen daily dosage in all three phases is 25 μg of 17α-ethinylestradiol; and the desogestrel daily dosage is 0.100 mg of desogestrel in the first phase, 0.125 mg of desogestrel in the second phase and 0.150 mg of desogestrel in the third phase.
 - 17. A triphasic oral contraceptive unit having 21 separate dosage units, adapted for successive daily oral administration comprising: 7 dosage units containing, in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen and a progestogen at contraceptively effective dosages corresponding in estrogenic activity to 23-28 μg of 17 α -ethinylestradiol and in progestogenic activity to 0.065-0.75 mg of norethindrone as a first phase; followed by 7 dosage units containing in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen and a progestagen at a contraceptively effective dosage corresponding in estrogenic activity to 23-28 μg of 17α -ethinylestradiol and in progestogenic activity to 0.25-1.0 mg of norethindrone as a second phase; followed by 7 dosage units containing in admixture with a pharmaceutically acceptable carrier, a combination of an estrogen at a contraceptively effective dosage corresponding in estrogenic activity to 23-28 μg of 17α -ethinylestradiol and in progestogenic activity to 0.35-2.0 mg of norethindrone as a third phase; and optionally containing 7 additional dosage units free of estrogen and progestogen; with the provisos that the progestin dose should increase from the first phase to the second phase to the third phase, that the progestin is desogestrel at a dose in each phase of between of from 0.05-1.0 mg/day and that the dosage of estrogen is kept constant in each phase.